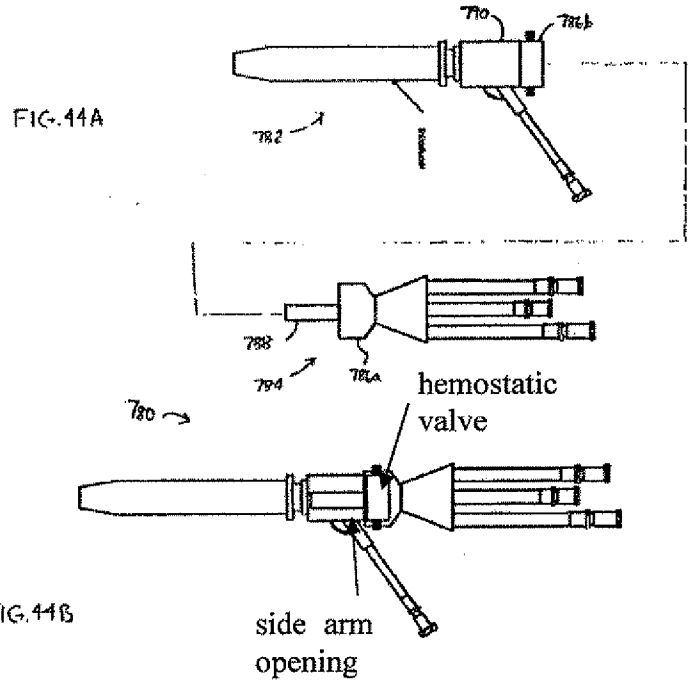
REMARKS

The amendments above and the remarks below are in response to an Office Action mailed on February 26, 2009. In the Office Action, Claims 1-5, 9-12, 15-16 and 19-20 were rejected under 35 U.S.C. 103(a) over U.S. Pats. Nos. 5,156,596 to Balbierz et al. ("Balbierz") and 5,092,846 to Nishijima et al. ("Nishijima") or 5,749,889 to Bacich et al. ("Bacich"). Claims 1 and 15 were also rejected under 35 U.S.C. 112, second paragraph, for an alleged lack of clarity of "immediately downstream" and the recitation of conversion to a multiple lumen access device. The drawings were also objected to as not showing these same features.

With respect to the rejection under 35 U.S.C. 112, the recitation "such that the introducer is converted from an infusion introducer to a multiple lumen access device by virtue of the main channel and the auxiliary channel in the junction housing" has been deleted from both Claim 1 and 15.

Also, Claims 1 and 15 have been amended to clarify the structure of the side arm, namely describing a side arm tube with a lumen that communicates with an opening immediately distal the hemostasis valve. Thus, a medical solution can flow through the side arm lumen, through the opening and into the access tube lumen immediately distal or below the hemostasis valve. This is already shown in the present application's Figures 44A and 44B, for example, as replicated below:



The term "immediately downstream" has therefore been replaced with a more clear description of "immediately distal" and is also shown in the drawings. The objections to the drawings and rejections under 35 U.S.C. 112 have therefore been overcome.

Notably, with the structure recited in Claims 1 and 15, any infusion of solution will flow through the side arm lumen and end up distal or below the valve and mix with blood that has flowed up through the introducer access tube to stop at the hemostasis valve.

Balbierz

An insertion assembly 11 shown in Figure 1 of Balbierz includes a needle hub 12 supporting a needle 18. The needle hub fits within an outer cannula hub 22 and the needle extends through an outer cannula 28 supported by the cannula hub. The needle and outer cannula are inserted into a vein and the needle withdrawn, leaving only the outer cannula. Col. 7; ll. 14-21 of Balbierz. The outer cannula hub includes a valve means 70, as shown in Figures 3 and 4 of Balbierz. The valve means 70 includes a self sealing septum 72.

Balbierz also discloses a multi-lumen catheter assembly 10, as shown in Figure 5. The multi-lumen catheter assembly 10 includes a positioning assembly 38 with Luer locking mechanism 66 that attaches it to the insertion assembly, as shown in Figures 3 and 4 of Balbierz. The catheter includes an inner cannula 52 with a distal end portion 56 "that extends beyond the distal end portion 32 of the outer cannula 28." Col. 7; ll. 45-47 of Balbierz. The other end of the inner cannula is fed by a proximal access region 48, as shown in Figure 4 of Balbierz.

Notably, inner cannula 52 extends from the side arm of the Y-shape through and out of the outer cannula without fluid communication between the lumen of the inner cannula and the outer cannula.

In contrast, the presently claimed invention recites a side arm opening immediately distal the hemostasis valve. For at least that reason, Balbierz alone does not teach or suggest the present invention as recited in the claims. In fact, it was admitted in the final Office Action that Balbierz does not teach a side arm opening distal of a hemostasis valve.

Nishijima

Nishijima discloses a catheter introducer that includes a body 2 defining an inner cavity 11 that is distal to a valve means 3, as shown in Figure 1B. A sheath tube 5 is connected to the body so that it communicates with the inner cavity. The body also includes a branching member 7 which is connected to a connecting tube 8 for the injection of heparin or saline into the inner cavity. A dilator 12 that is connected to a grip 13 can be inserted through the valve means for dilating openings. A catheter 4 can be inserted through the dilator, as shown in Figure 1A of Nishijima.

Nishijima, among other aspects, does not disclose a multi-function adapter for coupling a catheter to an infusion introducer. Therefore, Nishijima alone also does not teach or suggest the presently claimed invention.

Bacich

Bacich discloses a surgical access device 100 that includes a distal insertion portion 102 connected to a proximal housing portion 104, as shown in Figure 1. Figure 6 of Bacich illustrates a main channel 122 and a merge channel 162 that are held together in an "asymptotic" relationship by the housing portion. The channels 122, 162 each include duckbill valves 168, 166 and conduits 106, 108. The inflow conduit 106 opens distal to the duckbill valve 168 and into the main channel 122. The conduit 106 is an inflow conduit that may be used to "pass distension or irrigation media down the main channel 122 to the distal end of the access device 100." Col. 18; ll. 15-18 of Bacich.

Bacich, among other aspects, does not disclose a multi-function adapter for coupling a catheter to an infusion introducer. Therefore, Bacich alone also does not teach or suggest the presently claimed invention.

Alleged Combination of Balbierz and Nishijima or Bacich

One of ordinary skill in the art would not combine Balbierz and Nishijima or Bacich. As noted above, there is no fluid communication between the lumen of the inner and outer cannulae in Balbierz. Balbierz stresses the importance of this design several times. "The distal end portion 56 of the inner cannula 52, in the embodiment illustrated, extends beyond the distal end portion 32 of the outer cannula 28. In this manner non-compatible medicaments can be introduced into a

blood vessel or other body cavity a spaced distance apart from one another. Or, samples can be removed from a region of the vessel or cavity which is free of a particular medicament which is being introduced via another lumen." Col. 7; ll. 45-53 of Balbierz (emphasis added). Thus, the relationship of the inner and outer cannula of Balbierz is no motivation to combine the branching member 7 of Nishijima or the inflow conduit of Bacich with Balbierz.

In fact, Balbierz, when differentiating the prior art, teaches against introduction of liquids immediately distal of a septum (which is analogous to a valve) because of undesirable stagnation.

> Also, any liquids being flowed through the outer cannula lumen (i.e., through the annular space between the inner and outer cannulae) must be introduced downstream of the septum whereby the space immediately downstream of the septum (and upstream of the introduction of the liquid) is substantially stagnant. Furthermore, the fact that this space is not flushed out means that if the fluid being flowed through the outer cannula lumen is changed, there will be a transition time during which a mixture of the old and new fluids will be present. As some medicaments are not compatible with others such mixing can be undesirable.

See, col. 2, ll. 1-12 of Balbierz. Nishijima teaches this same structure that Balbierz deplores, its branching member connects to inner cavity 11 which is distal to the valve means 3, as shown in Figure 1B. Bacich also teaches the same structure, its conduit 106 opens distal to the valve 168, as shown in Figure 6.

Balbierz also stresses the importance of not introducing flow downstream of the valve. "It is also important to understand that flow from the second passage 42 into the outer cannula lumen 34 washes through and cleanses the valve means 70 thereby eliminating any dead space which would be present if the flow into the outer cannula lumen 34 was introduced downstream of the valve means 70."

Nishijima teaches the end of the branching member opening into the cavity 11 of the main body 2 which communicates with sheath tube 5. Bacich teaches the end of the inflow conduit 106 opening into a space distal the duckbill valve 168. Thus, one of ordinary skill in the art would view Nishijima and Bacich as both disclosing an assembly that causes mixing of non-compatible medicaments and stagnation of flow in the "dead space" immediately distal of a valve. One of skill in the art studying Balbierz' warnings about stagnation would set aside Nishijima and Bacich as incompatible references.

Thus, the present invention as recited in Claims 1 and 15 represents a surprising result over the teachings of the prior art. In particular, Claims 1 and 15 recite an access device with a multi-function adapter that that couples a catheter to an infusion introducer, wherein the infusion introducer includes a side arm lumen communicating with an opening positioned immediately distal of a hemostasis valve. The remaining Claims 4-5, 9-12 and 16-20 depend from, and further patentably distinguish, Claims 1 and 15. The rejection under 35 U.S.C. 103(a) has therefore been overcome.

CONCLUSION

In view of the remarks and amendments presented above, it is respectfully submitted that the pending claims of the present invention are in condition for allowance. It is respectfully requested that a Notice of Allowance be issued in due course. The Examiner is requested to contact Applicants' undersigned attorney to resolve any remaining issues in order to expedite examination of the present application.

The Commissioner is hereby authorized to charge the required fees for the **One-Month** extension of time to Deposit Account No. 50-1225. If an appropriate payment does not accompany or precede this submission, the Commissioner is hereby authorized to charge said fees, such as under 37 C.F.R. §§ 1.16 or 1.17, or to credit any overpayment, to Deposit Account No. 50-1225 referencing Attorney Docket No. ECC-5062CIP2DV.

Respectfully submitted,

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